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(71) Applicants: MICROVENA CORPORATION [US/US]; 1861 Buerkle Road, White Bear Lake, MN 55110-5246 (US). INFINITY EXTRUSION & ENGINEERING, INC. [US/US]; Building 6, 3350 Scott Boulevard, Santa Clara, CA 95054 (US).

(72) Inventors: WIESNER, Steven; 1183 Yarwood Court, San Jose, CA 95128 (US). WILKINS, Douglas; 989 Leo Drive, San Jose, CA 95129 (US). SEGERMARK, James; 3635 Big Fox Road, Gem Lake, MN 55110 (US).

(74) Agent: HOTCHKISS, Edward, S.; Fredrikson & Byron, P.A., 1100 International Centre, 900 2nd Avenue S., Minneapolis, MN 55402-3397 (US).

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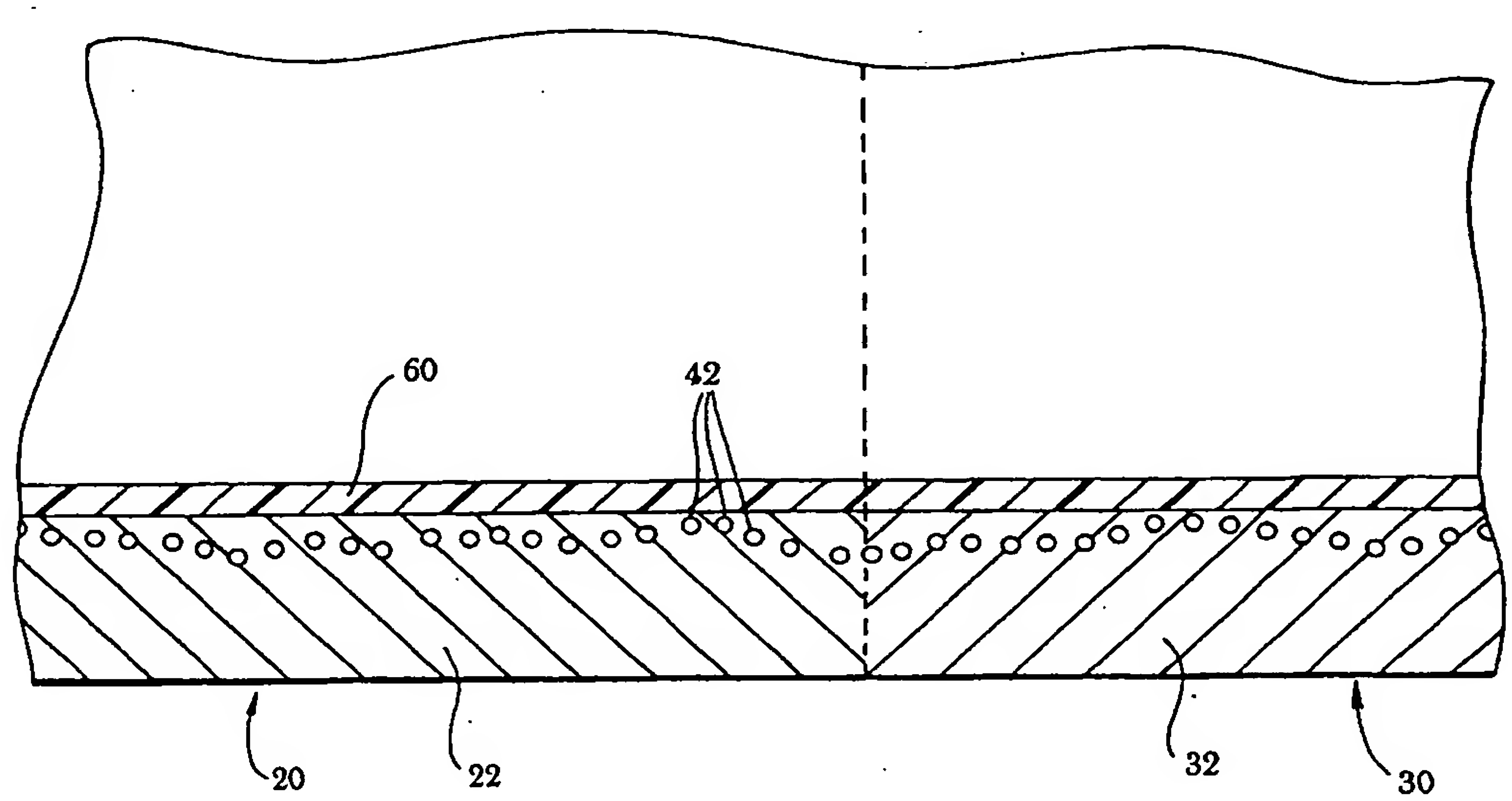

(57) Abstract

Improved multi-durometer catheter (10) and method of making said catheter (10) is disclosed. One catheter (10) of the invention includes proximal segment (20), distal segment (30), and elongate tubular reinforcing member (40) which is imbedded into inner surface of the proximal segment (20) along a distal length thereof, and is imbedded into an inner surface of the distal segment (30) along a proximal length thereof. Distal end (26) of proximal segment (20) is joined to proximal end (36) of the distal segment (30). The durometer of the plastic of proximal segment (20) may be greater than the durometer of the plastic of distal segment (30). In one method, catheter (10) is made by forming tubular proximal segment (20), tubular distal segment (30), and elongate tubular reinforcing member (40). Reinforcing member (40) is then imbedded into an inner surface of proximal segment (20) along a distal length thereof, and imbedded into an inner surface of distal segment (30) along a proximal length thereof. Distal end (26) of proximal segment (20) is joined to proximal end (36) of the distal segment (30).

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IMPROVED MULTI-DUROMETER CATHETER

FIELD OF THE INVENTION

The present invention provides both an improved catheter design and a method of manufacturing such a catheter. More particularly, the invention provides improvements in the design and manufacture of catheters having variable flexibility along their lengths.

BACKGROUND OF THE INVENTION

Catheters have found a wide range of applications in the medical fields. Some catheters, referred to as guide catheters, can be placed in a passageway in a patient's body without requiring any additional equipment. Such catheters tend to be steerable by orienting a pre-shaped distal length in a specific fashion. However, these catheters tend to be fairly rigid and it is difficult to negotiate a tortuous path along the patient's passageways with such catheters.

In reaching more selective sites in a patient's body, such as a specific site within a patient's vasculature, it is often necessary to use a guidewire. Guidewires are long metal wires which can be fairly easily steered into position. The distal end of some guidewires can be remotely manipulated during a position to help guide the wire through the desired vessels. Other guidewires have pre-formed distal ends which assist in steering them along the desired path.

Once the guidewire is properly positioned, a catheter can then be guided along the wire to the desired destination. In large, relatively straight passageways, this is fairly easily accomplished. As the path becomes more tortuous and the passageways more narrow, tracking along the guidewire becomes increasingly difficult. If a catheter does not have a high enough column strength, it will tend to buckle or kink along its length and the physician will not be able to urge the catheter forward within the patient's vessels. If the catheter is too stiff, though, it will not follow the twists and turns of the guidewire very readily and can even dislodge the guidewire from its carefully acquired position.

Several catheter designs have been proposed to provide sufficient "pushability" (i.e. ability to be pushed axially along the guidewire without buckling

or kinking), yet be sufficiently flexible to adequately track a guidewire along a fairly tortuous path. The most tortuous length of the path is typically along the distal length of the path. By making a proximal length of the catheter more stiff and a distal length more flexible, the physician can still urge the catheter into position while allowing the distal length of the catheter to closely track a guidewire through tortuous, narrow vessels.

For example, US Patent 4,739,768 (issued to Engelson in 1988), the teachings of which are incorporated herein by reference, suggests one catheter design which has a stiffer proximal length and a more flexible distal length. In this design, the proximal length of the catheter is formed of two layers of plastic, with one of the two layers terminating before the distal end of the catheter to provide a distal length with a single layer.

Others have proposed making catheters formed of a single layer, but having the composition of the catheter vary along its length. Oftentimes, such catheters are formed by forming two separate segments and heat fusing the ends of the two segments to one another to provide a single lumen. If so desired, this can be repeated several times along the length of the catheter to provide a catheter with multiple segments, each of which has differing degrees of flexibility.

SUMMARY OF THE INVENTION

The present invention contemplates both an improved catheter design and a method of making such a catheter. In one embodiment, a catheter of the invention includes an integrally formed tubular proximal segment, an integrally formed tubular distal segment and an elongate tubular reinforcing member. This reinforcing member is imbedded in the proximal segment along a distal length thereof and is imbedded in the distal segment along a proximal length thereof. A distal end of the proximal segment is joined to a proximal end of the distal segment. In one preferred design, the proximal and distal segments are formed of different plastic materials, with the durometer of the plastic of the proximal segment being greater than the durometer of the plastic of the distal segment.

In accordance with one method of the invention, a catheter is made by forming a tubular proximal segment, a tubular distal segment and an elongate tubular reinforcing member. Either at the time these segments are formed or in a later forming operation, the reinforcing member is imbedded in the proximal segment along a distal length thereof and imbedded in the distal segment along a proximal length thereof. The distal end of the proximal segment is joined to a proximal end of the distal segment, preferably in a fluid-tight joint. Preferably, the reinforcing member is imbedded into the inner surfaces of the proximal and distal segments and the distal and proximal segments are joined to one another in the same manufacturing step. If so desired, the reinforcing member can have apertures therein and the material of the proximal and distal segments may be allowed to flow into those apertures when imbedding the reinforcing member in the inner surfaces of those segments.

According to an alternative method of the invention, a tubular braid having apertures therethrough is placed loosely on a mandrel and attached to the mandrel adjacent the braid's proximal and distal ends. The braid is left loose on the mandrel to permit plastic to flow between the braid and the mandrel. A first plastic material is extruded over the mandrel and the tubular braid to define a proximal segment having a distal end. The first plastic material is permitted to flow through the apertures in the tubular braid before the plastic cools below its melt softening point to imbed the tubular braid in the proximal segment. A second plastic material is extruded over the mandrel and the tubular braid to define a distal segment having a proximal end abutting the distal end of the proximal segment. The second plastic material is permitted to flow through the apertures in the tubular braid before the plastic cools below its melt softening point to imbed the tubular braid in the distal segment. The distal segment bonds to the proximal segment as it cools. The resulting structure is then removed from the mandrel.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic cross sectional view of elements of a catheter of the invention prior to assembly;

Figure 2 is a schematic cross sectional view of a catheter of the invention manufactured using the elements of Figure 1;

Figure 3 is a schematic cross sectional, isolational view of a portion of the catheter of Figure 2;

Figure 4 is a schematic cross sectional, isolational view of the elements of Figure 1 arranged on a mandrel for formation of the catheter of Figures 2 and 3;

Figure 5 is a schematic cross sectional view, similar to Figure 2, of an alternative catheter of the invention;

Figure 6 is a schematic cross sectional, isolational view, similar to Figure 3, of a portion of the catheter of Figure 5; and

Figure 7 is a schematic cross sectional, isolational view of a portion of the catheter of Figure 5 arranged on a mandrel for formation.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning first to Figures 1-3, the present invention provides a catheter 10 having variable flexibility along its length and a method of making such a catheter. This catheter is formed of a tubular proximal segment 20, a tubular distal segment 30, and a tubular reinforcing member 40. As illustrated in Figure 1, each of these three segments is desirably formed separately and later joined together into the final catheter 10 (illustrated in Figure 2).

The proximal segment 20 is generally tubular, having a wall 22 defining an internal lumen 24. Although varying cross-sectional shapes could be used, it is preferred that the wall 22 be generally annular in cross section, defining a generally circular lumen 24. The diameter of this segment can be changed for different clinical applications, and can even vary along the length of the proximal segment if so desired. Catheters having proximal segments of about 3-12F (about 1.0-4.0 mm outer diameter) can readily be made in accordance with the invention. The length of this proximal segment can be selected to achieve any suitable design objective. In a typical design, it is anticipated that the proximal segment will be substantially longer than the distal segment 30. A proximal

segment having a length of about 80-140 cm would be appropriate for many applications.

The distal segment 30 is also generally tubular. Like the proximal segment, it includes a wall 32 defining a lumen 34 therein. The dimensions and shape of the wall 32 and lumen 34 should be very similar (if not substantially identical) to the dimensions and shape of the wall 22 and lumen 24 of the proximal segment 20, at least adjacent their junction. For example, if the proximal segment is about 3F, so should be the distal segment; if the proximal segment is about 12F, so should be the distal segment. Each of these segments can vary in dimensions along their length if desired. For reasons made clear below, though, it is important that they have substantially the same dimensions where they abut one another.

In the illustrated embodiments, the distal end 38 of the distal segment 30 is provided with a rounded tip. This would provide a more blunt, atraumatic shape to the distal end of the catheter when it is finally assembled. In use, this will help minimize any damage to the intima of the vessels in which the catheter 10 is deployed. A distal segment having a length on the order of about 2-25 cm should be suitable for many common applications, with a length of under 5 cm being preferred for many guide catheters.

The proximal segment 20 and distal segment 30 may be formed of any suitable material. Preferably, both of these segments are formed of a plastic material, with the plastic material of the proximal segment being different from the plastic material of the distal segment. Ideally, both of these plastic materials are thermoplastics which can flow at elevated temperatures.

A wide range of plastic materials for use in medical catheters are known in the industry. For example, commercially available medical catheters have been formed using various silicones, polyethylenes, polyurethanes, polypropylenes, polyether block amides, and polytetrafluoroethylenes. An exhaustive listing of possible catheter materials is beyond the scope of this disclosure. Those in the field will be well aware of a large number of suitable materials for use in

constructing catheters and a wide variety of plastic materials having specific properties are commercially available in the catheter industry.

While the specific material used to manufacture the proximal segment 20 and distal segment 30 may not be critical, in one preferred embodiment the relative properties of the materials used to form these two segments is of importance. In particular, the proximal segment 20 is desirably formed of a first plastic material having a first durometer while the distal segment 30 is formed of a second plastic material having a second durometer. Ideally, the first durometer is higher than the second durometer, yielding a proximal segment 20 which is stiffer than the distal segment 30.

A stiffer proximal segment provides a number of advantages. Not least among those advantages is improved column strength, which improves "pushability", i.e., the ability to urge the catheter along a vascular channel for deployment without having it buckle. A softer distal segment 30 also has advantages. A more supple, flexible distal segment will more readily track a guidewire along a more tortuous path. If the distal segment 30 is too stiff, it may have difficulty negotiating sharp, angular turns which are necessary to reach many superselective sites. In addition, a softer distal segment will minimize trauma to the intima of the vessel in which the catheter is deployed.

Other than the difference in durometer, the first plastic material of the proximal segment 20 and the second plastic material of the distal segment 30 of this embodiment desirably have similar chemical properties. For reasons discussed more fully below, the first and second plastic materials should be compatible with one another and capable of flowing into one another when heated. In a preferred embodiment, the first and second plastic materials have generally the same chemical composition, but have different durometers, such as by using a higher molecular weight material in the proximal segment than in the distal segment.

Preferably, the difference between the melt softening point of the first and second plastic materials is no more than about 20% of the melt softening point of the first plastic material, with a maximum difference of no more than about 10%

being preferred. For example, if the melt softening point of the first plastic material is about 325°F (about 163°C), the melt softening point of the second plastic material is preferably between about 260°F (about 126°C) and about 390°F (about 199°C), with a range of about 292°F (about 144°C) to about 358°F (about 181°C) being preferred. In one suitable catheter made in accordance with the invention, the proximal segment may be formed of 72D Pebax, which has a melt softening point of about 325°F (about 163°C), while the distal segment is formed of a 35D Pebax, which has a melt softening point of about 310°F (about 154°C). (Pebax is a trade name for a polyether block amide resin commercially available from Atochem Corporation, Pennsylvania, USA.)

The tubular reinforcing member 40 has a proximal end 46 and a distal end 48. For ease of illustration, this reinforcing member is shown in the drawings as being relatively short. It should be understood that the length of this reinforcing member can be varied fairly widely, though. In one preferred embodiment, for example, the reinforcing member is longer than the proximal segment 20 and, when the catheter 10 is assembled, extends along the entire length of the proximal segment and about half of the length of the distal segment 30.

The reinforcing member can be formed of any desired material to yield a final assembled catheter 10 with desired properties. It is important to realize that the properties of the reinforcing member itself are less important than are the properties of the reinforcing member when imbedded in the proximal and distal segments 20, 30 as shown in Figure 2 and discussed in more detail below. Preferably, the reinforcing member increases column strength of the catheter along the length in which it is imbedded. Desirably, it also improves hoop strength along this length, making the catheter less likely to rupture under increased internal pressures and enabling higher flow rates of fluids (e.g. contrast media or balloon inflation fluids) through the lumen of the catheter.

Making the reinforcing member 40 stiffer (at least axially) and stronger (at least in terms of hoop strength) than one or both of the proximal and distal segments can obviously accomplish both of these goals. However, that should not be necessary. Even a very floppy reinforcing member can have a significant

impact on the physical properties of the assembled catheter 10. A wide range of materials can be used as the reinforcing member 40, including plastic materials commonly employed in catheter manufacture or, in some embodiments.

In one embodiment of a catheter 10 of the invention, the reinforcing member 40 is a tubular braid. Such braids are well known in the art and need not be described in detail here. Generally speaking, though, tubular braids include a plurality of strands 42 of a selected material, with one set of strands being helically wound in one direction and a second set of strands being helically wound in an opposite direction or "hand". Weaving these two sets of strands together about a forming mandrel yields a tubular fabric. Machines for commercially manufacturing tubular braids are commercially available from Wardwell, Inc. and Steiger, Inc., among others.

In a preferred embodiment, the tubular braid used as the reinforcing member 40 is formed of strands 42 of a material which desirably has a higher hield strength than the plastic used to form either the proximal segment 20 or distal segment 30. Most metals would suffice for this application, with typical metals for such a tubular braid reinforcing member 40 including stainless steel and Nitinol, a nickel-titanium alloy which exhibits "superelastic" properties. If so desired, the reinforcing member could instead be formed of a plastic material such as a high density polyamide, polyester, or Kevlar™, a commercially available aromatic polyamide fiber. The individual strands will typically be on the order of about 0.001-0.002 inches (about 0.025-0.05 mm) in diameter, but that diameter can be varied to vary the stiffness of the wires and, hence, the resulting braid.

This reinforcing member 40 desirably is formed with a plurality of apertures 50 therein. If the reinforcing member is a tubular braid, the strands 42 will typically be spaced apart from one another in a fairly open weave and the spaces between adjacent strands will define apertures through the "wall" of the reinforcing member. The size and shape of these apertures can be controlled by controlling the diameters of the strands 42 used to form the braid, the pitch of the wire strands (i.e. the angle defined between the turns of the wire and the axis of

the braid) and the pick of the fabric (i.e. the number of turns per unit length). Assuming a constant strand diameter, the higher the pick and the pitch of the fabric, the smaller will be its apertures. One suitable tubular braid for use in connection with the present invention can be formed of about 16 stainless steel strands, each having a diameter of about 0.001 inch (about 0.025 mm) diameter, at a pitch of about 52° and a pick of about 60.

If the tubular reinforcing member 40 is instead formed of an extruded length of a plastic material, for example, the desired apertures can be formed by piercing the wall of the tube. In order to promote efficient, reliable manufacture of the catheter 10, care should be taken to ensure that these apertures are large enough and are present in sufficient number to allow the plastic materials of the proximal and distal segments 20, 30 to flow into the apertures during assembly, as discussed below.

When assembled, as shown in Figures 2 and 3, the walls 22, 32 of the proximal and distal segments 20, 30 are aligned with one another. This aligns the lumens 24, 34 of these two segments, providing the catheter with a single elongate lumen 14 extending through both segments. The distal end 26 of the proximal segment is joined to the proximal end 36 of the distal segment. These two ends are desirably heat fused in a manner described below wherein the material of the proximal segment flows into the material of the distal segment, yielding a zone where the two materials are mixed together to some extent. Since the distal end of the proximal segment and proximal end of the distal segment are melded into this zone, in Figure 2 the melded distal length of the proximal segment is designated 26′ while the melded proximal length of the distal segment is designated 36′. This joint should be fluid-tight and capable of withstanding the rigors of the intended use for the catheter.

The proximal segment 20 is shown as extending proximally beyond the proximal end 46 of the tubular reinforcing member 40, but this need not be the case. Ideally, the reinforcing member 40 extends along the entire length of the proximal segment, as noted above. However, the distal segment 30 does desirably extend distally beyond the distal end 48 of the reinforcing member 40.

The distance which the reinforcing member extends along the distal segment can be varied widely.

The reinforcing member desirably extends along at least the proximal quarter of the distal segment 30, though. This will ensure that the reinforcing member extends beyond the melded proximal length 36′ of the distal segment and promotes a strong, reinforced joint between the proximal and distal segments. More typically, the reinforcing member will extend along about one half of the length of the distal segment. This will still allow a length of the distal segment 30 to extend distally beyond the reinforcing member, providing the catheter with a soft, atraumatic distal end 38.

The reinforcing member 40 is imbedded in the wall of the proximal segment 20 along a distal length thereof and imbedded in the wall of the distal segment 30 along a proximal length thereof. In the catheter of Figures 2 and 3, the plastic material of each of these segments 20, 30 extends into the apertures 50 in the reinforcing member. This will help keep the reinforcing member 40 in place in the catheter. As can be seen in the schematic drawing of Figure 3, at least portions of an inner surface of the reinforcing member will remain exposed to the lumen of the catheter. By way of contrast, in the catheter 10 of Figure 5 the tubular braid is substantially completely imbedded within the wall of the catheter.

In common catheters reinforced with a tubular braid, the tubular braid is sandwiched between two separate layers, which are bonded to one another with an adhesive. This requires the manufacturer to form two thin layers along the entire length of the catheter (which increases costs and tends to reduce manufacturing tolerances) and to perform additional steps in assembling the catheter. This is deemed necessary to constrain the tubular braid in the event the catheter wall fails. Tubular braids have a tendency to unravel, leaving a frayed collection of wire strands, and such constraints are deemed necessary to prevent the braid from flaring out and potentially damaging the vessel walls. Even so, such catheters frequently fail by "delaminating", wherein the two thin layers separate from one another.

Imbedding a tubular braid reinforcing member 40 in an inner surface along the lumen 14 of the catheter allows the walls 22, 32 of the proximal and distal segments to constrain the braid from flaring outwardly into contact with the vessel walls. In order to be so exposed, essentially the entire thickness of the catheter wall would need to rupture. Since the rest of the length of the braid would still be imbedded, the area which would flare out in this fashion would still be significantly limited. As explained more fully below, this structure can be formed using proximal and distal segments formed in a single layer. This promotes better manufacturing tolerances and helps simplify manufacturing, thereby helping control manufacturing costs.

As noted above, in one preferred embodiment, at least a portion of the inner surface of a tubular braid reinforcing member 40 is exposed to the lumen 14 of the catheter. This exposure often will be uneven due to the manufacturing process detailed below, i.e. some of the strands may be completely imbedded in the wall of the catheter while others are significantly exposed. In addition, given the fact that the strands are woven over and under one another, each strand will, obviously, have to be separated from the mandrel along at least portions of its length. However, an innermost surface of many of the strands 42 making up the braid will be exposed to the lumen of the catheter. This unevenness is schematically illustrated in Figure 3, where the plastic material extends between adjacent strands of the braid to a different depth at different locations.

Having the reinforcing member 40 exposed to the lumen of the catheter in this fashion offers some interesting design options. If the material of the reinforcing member is more abrasion resistant that the material of one or both of the proximal and distal segments 20, 30, the reinforcing member can serves as something of a bearing in high-friction applications.

For example, in mechanical thrombectomy applications, a drive shaft is rotated within a catheter at rather high speeds, building up substantial friction between the drive shaft and the wall of the catheter. Those portions of an abrasion-resistant reinforcing member 40 exposed to the lumen 14 of the catheter can serve as a bearing surface for such a drive shaft. In those fairly limited areas

where a thin layer of the plastic material may cover the inner surface of a length of a particular wire strand, friction may wear away that thin covering of plastic, thereby exposing that area of the reinforcing member.

Figures 5 and 6 illustrate an alternative embodiment of a catheter 110 in accordance with the present invention. As noted immediately above, the catheter shown in Figures 2 and 3 optimally has a portion of the reinforcing member 40 exposed to the lumen of the catheter. In the embodiment shown in Figures 5 and 6, though, the reinforcing member is not so exposed. Instead, the reinforcing member is substantially completely embedded in the wall of the catheter.

The embodiment shown in Figures 5 and 6 includes a separate liner 60 which desirably lines the entire lumen 14 of the catheter. This liner may be formed of a suitable flexible plastic material and desirably offers a relatively low friction surface to make it easier to deploy the catheter over the guidewire. A liner formed of polytetrafluoroethylene, Pebax, polyethylene or polyimide at about 0.001 inches to about 0.003 inches should serve this end well. Figure 6 is a close-up view of the junction between the proximal and distal segments 20, 30 in schematic form. (As explained previously, the junction between these two segments will ordinarily result in some co-mingling of the materials used to form this junction, yielding a melded distal length of the proximal segment 26' and a melded proximal length of the distal segment 36', as shown in Figure 5. For purposes of clarity, this melded zone is omitted from Figure 6 (it also was omitted from Figure 3).

In conventional catheter manufacture, it is common to sandwich a tubular braid between two layers of the catheter, as noted above. In such designs, the tubular braid serves as a spacer between the two thin plastic layers, with an adhesive being used to attach the two layers to the braid and, to a lesser extent, to one another. In the embodiment shown in Figures 5 and 6, though, the reinforcing member does not stand between the liner 60 and the rest of the catheter. Instead, the reinforcing member is substantially entirely embedded within the wall 22 of the proximal segment and wall 32 of the distal segment. This permits those walls 22, 32 to directly contact the liner 60. To promote adhesion

between the walls 22, 32 and the underlying liner 60, the outer surface of the liner (i.e., the surface in contact with the walls 22, 32) can be provided with an uneven texture. For example, if the liner is formed of polytetrafluoroethylene, the outer surface can be provided with a suitable texture by chemically etching, such as with TetraEtch, a trade name of a polytetrafluoroethylene etching compound commercially available from DuPont.

In the catheter illustrated in Figure 3, the wire strands 42 of the tubular braid are relatively uniformly positioned. Although this schematic diagram may exaggerate the uniformity of the position and spacing of the wires, the fact that the braid is pulled taut in the manufacturing process (described below), will help standarize those aspects of the braid.

In contrast to that regularity, the embodiment shown in Figures 5 and 6 have a tubular braid which is more uneven. As best seen in Figure 6, both the relative spacing of the wire strands and their radial distance from the axis of the catheter vary noticeably. Much like Figure 3, this schematic drawing may exaggerate the irregularity for purposes of illustration, but the tubular braid used to form this embodiment is left loose on the mandrel (as described below), permitting the wire strands to move more freely with respect to one another.

In essence, the resulting catheter has a reinforcing member embedded in the wall 22 of an integrally formed proximal segment 20 and in the wall 32 of an integrally formed distal segment 30. The liner 60 can be included, as shown in the drawings, or can be completely omitted if so desired. This structure is less likely to delaminate than is a standard multi-layer catheter reinforced with a tubular braid. In standard designs, the tubular braid is positioned between the inner and outer layers and impedes effective bonding between the two layers.

In addition, the design shown in Figures 5 and 6 reduces the effects of delamination if the liner 60 were to delaminate from the rest of the catheter. In prior art designs, when the two layers of the catheter delaminate, the tubular braid which was previously restrained between the two layers is free to move. Depending on where the delamination occurs and the condition of the tubular braid after delamination, this can increase the risk of both additional delamination

and having the wire braid protrude through the catheter wall. By substantially completely embedding the entire tubular braid within the integrally formed walls 22, 32 of the proximal and distal segments, any delamination which does occur will be completely unaffected by the braid. Accordingly, the braid will not help propagate the delamination and the braid will continue to be securely retained within the plastic within which it is embedded rather than being permitted to move relatively freely between the delaminated layers of prior art designs.

As noted above, the present invention also provides a method of manufacturing a catheter. For purposes of convenience, this method will be discussed below in connection with the same Figures 1-3, 5 and 6 used to illustrate two preferred embodiments of a catheter of the invention. Although the present method can certainly be used to manufacture such catheters, it should be understood that this method can be used to manufacture a range of alternative designs, as well.

In accordance with the present method, a proximal segment 20 is formed of a first material and the distal segment 30 is formed of a second, different material. As discussed above, these proximal and distal segments are desirably formed of different thermoplastic materials, with the durometer of the first plastic material used to form the proximal segment 20 being higher than that of the second plastic material used to form the distal segment 30. As also detailed above, the melt softening points of these two materials are desirably relatively close to one another, with the melt softening point of the first plastic material differing from that of the proximal segment by no more than about 20%, and ideally no more than 10%, of the melt softening point of the first plastic material. If a metal reinforcing member 40 is used, both of these segments are desirably formed of plastic materials which wet metal fairly readily.

Both the proximal segment 20 and the distal segment 30 may be formed using extrusion techniques common in the catheter manufacturing industry. Most commonly, these plastics will be extruded into long, continuous tubes and can be cut to appropriate lengths prior to assembly into the final catheter. As explained

above, the proximal segment will typically be about 100-150 cm long while the distal segment will typically be about 5-10 cm long.

The method of forming the tubular reinforcing member 40 will vary depending on the nature of the reinforcing member being used. For example, if the reinforcing member is a continuous extruded plastic material, the material may be extruded and apertures 50 may be formed through the wall of the extruded tube. If a metallic tubular braid is used, the tubular braid may be formed on a mandrel using a tubular braiding machine, as noted above.

The proximal and distal segments 20, 30 are then joined to one another and the reinforcing member 40 is imbedded in the wall of each of these two segments. Preferably, all of these attachments are formed in a single step by positioning all three of these parts on a forming mandrel and melding them into a single catheter 10.

Figure 4 schematically illustrates a catheter 10 of the invention assembled on a forming mandrel 60 during this stage of the manufacturing process. Forming catheters on mandrels is a common technique in the art and those in the field will readily understand how to carry out such techniques. Even so, a basic discussion of such mandrel forming techniques may be useful.

One can use a low friction plastic material having a melting point or melt softening temperature higher than the temperatures necessary to form the catheter on the mandrel. Such mandrels are commonly formed of polytetrafluoroethylene. Such mandrels are advantageous in that the formed catheter can usually simply be pulled off the mandrel because the catheter will not stick to the mandrel and will slide along the mandrel fairly readily.

Unfortunately, the high temperatures encountered in catheter formation can soften or deform plastic mandrels, increasing manufacturing tolerances. If precise dimensions of the catheter, particularly the size of the lumen, are important, mandrels formed of a stiff, temperature resistant material, such as a metal, are preferred. Oftentimes, such metal mandrels are formed of a ductile metal and may be coated with a second metal to minimize adhesion of the catheter to the mandrel. For example, a copper mandrel may be coated with

silver, with silver being employed because many plastics adhere to silver less readily than to copper. Once the catheter is formed on the mandrel, the ends of the mandrel can be pulled apart to stretch the mandrel and reduce its diameter. The catheter can then be fairly readily removed from the mandrel.

In accordance with this embodiment of the invention, the three components of the catheter shown in Figure 1 - the proximal segment 20, distal segment 30 and reinforcing member 40 - are assembled on the mandrel M. First, the reinforcing member is placed over the mandrel. To make the catheter shown in Figures 2 and 3 with a tubular braid exposed to the lumen, the braid is pulled taut by pulling the ends away from one another. This will both elongate the braid and reduce its diameter, pulling it snugly against the surface of the mandrel.

The proximal segment and distal segment may then be positioned over the reinforcing member, taking care to position these elements so that the distal end 48 of the reinforcing member is at the appropriate position along the distal segment. In the drawings, a significant space is illustrated between the adjacent ends of the proximal segment 20 and distal segment 30, as well as between the inner surface of these elements and the outer surface of the mandrel M. In actuality, the distal end 26 of the proximal segment and the proximal end 36 of the distal segment are positioned immediately adjacent one another and desirably abut one another.

While the proximal and distal segments 20, 30 may be sized to make them fit snugly on the mandrel, this will make it rather difficult to slide them along the mandrel into the desired position. Accordingly, the inner diameters of these segments 20, 30 desirably are slightly larger than the combined outer diameter of the mandrel and the braid. Typically, providing the proximal and distal segments with lumens about 0.002-0.005 inches (about 0.05-0.13 mm) larger than the outer diameter of the braid/mandrel combination will permit one to slide these segments into place and simply heat the elements to create the desired structure, as described immediately below. If the size difference is more significant, e.g., up to 0.015 inches (about 0.38 mm), one would likely need to heat the assembly and either draw it through a die or shrink a tube over the exterior of the catheter to

make sure the plastic of the walls 22, 32 flows into the spaces in the reinforcing member 40.

Once these elements are assembled on the mandrel, they can be heated for a predetermined time in accordance with a predetermined heat treatment profile. During this heat treatment, the proximal and distal segments (at least those lengths of these segments positioned adjacent one another on the mandrel) are heated to a temperature sufficient to heat fuse them to one another. If a thermoplastic material is used, a zone of each segment is heated to a temperature above the higher melt softening point of the two materials, permitting the two materials to flow together. This will join the distal end 26 of the proximal segment to the proximal end 36 of the distal segment, as shown in Figures 2 and 3.

If a tubular braid reinforcing member 40 is pulled taut on the mandrel M, its inner surface will be in contact with the mandrel when the first and second plastic materials are softened and flow. The plastic material will be inhibited from coating the portions of the reinforcing member in contact with the mandrel, but the plastic can flow into the apertures 50 in the reinforcing member until it contacts the mandrel. This promotes a relatively smooth lumen 14 of the catheter while leaving at least a portion of an inner surface of the reinforcing member 40 exposed to this lumen.

Figure 7 schematically illustrates a method of manufacturing the catheter 110 shown in Figures 5 and 6. If the catheter is to include a liner 60 for its lumen, this liner will typically be extruded directly onto the mandrel. This can be done, for example, by drawing the mandrel through an extrusion die with a diameter only slightly larger than the outer diameter of the mandrel.

As in the embodiment shown in Figure 4, the reinforcing member can then be applied between the mandrel and the walls 22, 32 of the proximal and distal segments. As explained previously, the tubular braid 40 shown in Figure 4 is pulled relatively tautly down onto the mandrel, yielding a relatively even spacing of the wire strands along the mandrel and helping maintain most of the wire strands directly in contact with the mandrel along much of their length.

The reinforcing member utilized in the embodiment of Figure 7 is left relatively loose so that plastic can flow through the apertures 50 and beneath the reinforcing member to embed it in the walls. If the reinforcing member is a tubular braid, as shown in Figures 5-7, the tubular braid can be affixed to the mandrel (or to the liner 60 if such a liner is used) adjacent the braid's proximal and distal ends. Although the same thing can be done in the method illustrated in Figure 4, the braid is not pulled taut on the mandrel in Figure 7. Instead, it is left with some slack so the wires will be more loosely retained on the mandrel. This looseness will permit plastic to flow beneath the wires and encase the braid in the wall of the catheter.

Once the component parts of the catheter 110 are assembled on the mandrel M as schematically shown in Figure 7, they may be heated in essentially the same manner discussed above in connection with Figure 4. This will yield a catheter having a structure substantially as shown in Figures 5 and 6.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A catheter comprising an integrally formed tubular proximal segment having a wall and a lumen, an integrally formed tubular distal segment having a wall and a lumen, and an elongate tubular reinforcing member; the reinforcing member being imbedded in the wall of the proximal segment along a distal length thereof and being imbedded in the wall of the distal segment along a proximal length thereof, a distal end of the proximal segment being joined to a proximal end of the distal segment.
2. The catheter of claim 1 further comprising a liner lining a length of the lumen of the proximal segment and lining a length of the lumen of the distal segment.
3. The catheter of claim 2 wherein the liner is formed of polytetrafluoroethylene.
4. The catheter of claim 2 wherein the liner extends along substantially the entire length of the catheter.
5. The catheter of claim 1 wherein the durometer of the distal segment is lower than the durometer of the proximal segment.
6. The catheter of claim 5 wherein the melt softening point of the material forming the proximal segment and the melt softening point of the material forming the distal segment differ by no more than about 10% of the melt softening point of the material forming the proximal segment.
7. The catheter of claim 1 wherein the reinforcing member is a tubular braid.
8. The catheter of claim 7 wherein the tubular braid is formed of a harder material than the material used to form either the proximal segment or the distal segment.
9. The catheter of claim 8 wherein at least a portion of an inner surface of the tubular braid is left exposed to a lumen of the catheter along at least one of the distal and proximal segments
10. The catheter of claim 8 wherein the tubular braid is formed of a plurality of strands of metal.

11. The catheter of claim 1 wherein the distal segment extends distally beyond a distal end of the reinforcing member.

12. The catheter of claim 1 wherein the distal end of the proximal segment and the proximal end of the distal segment are fused into a fluid-tight joint.

13. A catheter comprising a tubular proximal segment having a wall and a lumen and being integrally formed of a first plastic material having a first durometer; a tubular distal segment having a wall and a lumen and being integrally formed of a second plastic material having a second durometer, the first durometer being greater than the second durometer; and an elongate tubular braid imbedded in the proximal segment along a distal length thereof and imbedded in the distal segment along a proximal length thereof; a distal end of the proximal segment being joined to a proximal end of the distal segment.

14. The catheter of claim 13 further comprising a liner lining a length of the lumen of the proximal segment and lining a length of the lumen of the distal segment.

15. The catheter of claim 14 wherein the liner is formed of polytetrafluoroethylene.

16. The catheter of claim 14 wherein the liner extends along substantially the entire length of the catheter.

17. The catheter of claim 13 wherein the melt softening points of the first plastic material and the second plastic material differ by no more than about 10% of the melt softening point of the first plastic material.

18. The catheter of claim 13 wherein the distal segment extends distally beyond a distal end of the reinforcing member.

19. The catheter of claim 13 wherein the reinforcing member is a tubular braid.

20. The catheter of claim 19 wherein the tubular braid is formed of a harder material than the material used to form either the proximal segment or the distal segment.

21. The catheter of claim 20 wherein at least a portion of an inner surface of the tubular braid is left exposed to a lumen of the catheter along at least one of the distal and proximal segments

22. The catheter of claim 20 wherein the tubular braid is formed of a plurality of strands of metal.

23. The catheter of claim 13 wherein the reinforcing member is a tube formed of a plastic material which is stiffer than either the first plastic material or the second plastic material.

24. A method of manufacturing a catheter comprising:
   a. integrally forming a tubular proximal segment;
   b. integrally forming a tubular distal segment;
   c. forming elongate tubular reinforcing member;
   d. imbedding the reinforcing member in the proximal segment along a distal length thereof;
   e. imbedding the reinforcing member into an inner surface of the distal segment along a proximal length thereof; and
   f. joining a distal end of the proximal segment to a proximal end of the distal segment.

25. The method of claim 24 further comprising forming a liner on a mandrel and applying the tubular reinforcing member over the liner prior to imbedding the reinforcing member into the proximal or distal segment.

26. The method of claim 24 wherein the tubular proximal segment is formed of a first plastic material having a first durometer and the tubular distal segment is formed of a second plastic material having a second durometer, the first durometer being greater than the second durometer.

27. The method of claim 24 wherein the tubular reinforcing member is formed to define a plurality of apertures in a wall thereof.

28. The method of claim 27 wherein the tubular reinforcing member is formed by braiding a plurality of strands into a tubular braid, the apertures comprising openings between the strands of the braid.

29. The method of claim 27 wherein the reinforcing member is imbedded in the inner surface of the proximal segment by allowing the material of the proximal segment to flow into said apertures.

30. The method of claim 29 wherein the proximal segment is heated to permit it to flow into said apertures.

31. The method of claim 24 wherein at least a portion of an inner surface of the reinforcing member is left exposed to a lumen of the catheter along at least one of the distal and proximal segments.

32. The method of claim 24 wherein the tubular reinforcing member is imbedded in the inner surface of the distal segment along only a proximal length thereof, leaving a distal length of the distal segment to extend distally beyond a distal end of the reinforcing member.

33. A method of forming a catheter comprising:

a. forming a tubular proximal segment of a first plastic material having a first durometer;

b. forming a tubular distal segment formed of a second plastic material having a second durometer, the first durometer being greater than the second durometer;

c. forming a tubular reinforcing member with a plurality of apertures therein;

d. imbedding the reinforcing member being into an inner surface of the proximal segment along a distal length thereof by allowing the first plastic material to flow into said apertures;

e. imbedding the reinforcing member into an inner surface of the distal segment along a proximal length thereof by allowing the first plastic material to flow into said apertures; and

f. joining a distal end of the proximal segment to a proximal end of the distal segment.

34. A method of forming a catheter comprising:

a. placing on a mandrel a tubular braid having apertures therein and attaching the tubular braid to the mandrel adjacent proximal and

distal ends of the tubular braid, leaving the tubular braid loose on the mandrel to permit plastic to flow between strands of the tubular braid and the mandrel;

b. placing over a proximal portion of the tubular braid a proximal tubular member formed of a thermoplastic material having a melt softening point, the proximal tubular member having a distal end;

c. placing over a distal portion of the tubular braid a distal tubular member formed of a thermoplastic material having a melt softening point, the distal tubular member having a proximal end which is positioned immediately adjacent the distal end of the proximal tubular member;

d. heating the proximal and distal tubular members above their respective melt softening points;

e. allowing the proximal end of the distal tubular member to bond to the distal end of the proximal tubular member;

f. permitting the first and second thermoplastic materials to flow through the apertures in the tubular braid before allowing the first and second thermoplastic materials to cool below its melt softening point to imbed the tubular braid in the proximal and distal tubular members; and

g. removing the structure so formed from the mandrel.

35. The method of claim 34 further comprising forming a liner on the mandrel prior to placing the braid on the mandrel.

36. The method of claim 35 wherein the liner is formed by casting a thin film of a plastic material directly on a surface of the mandrel.

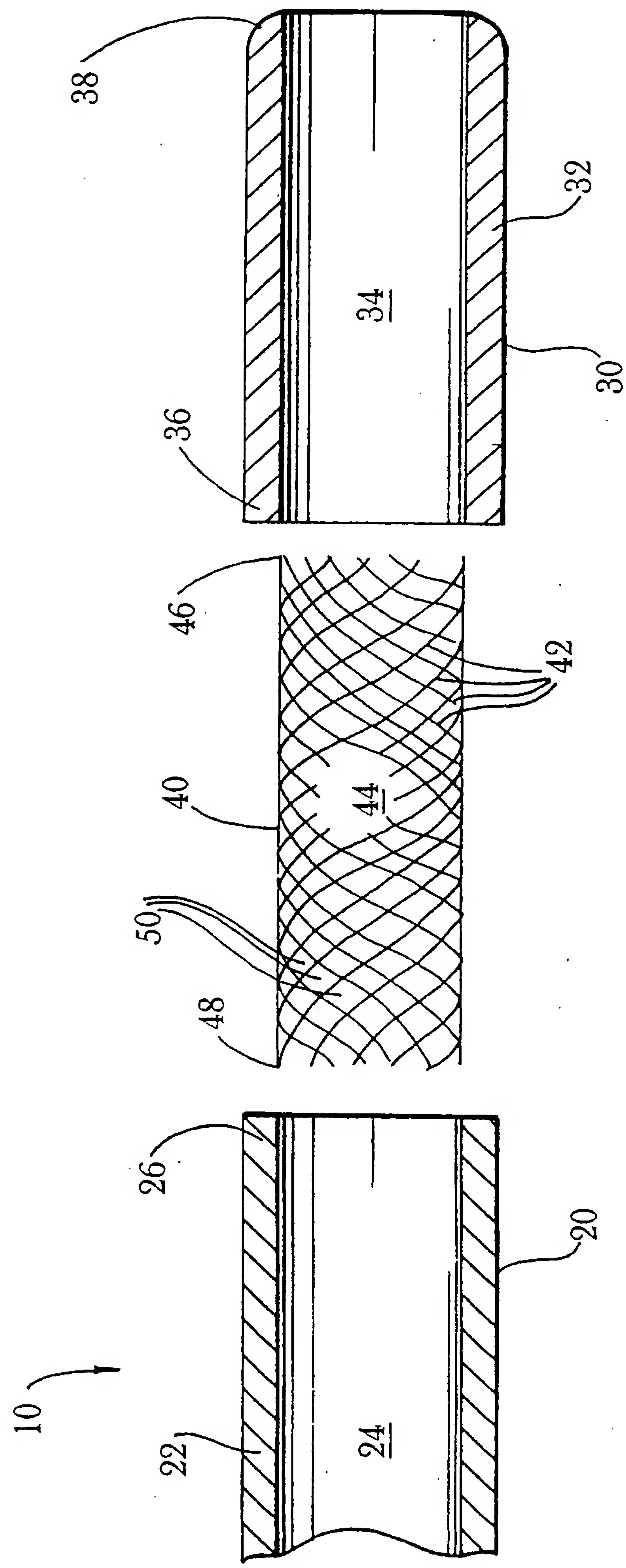


Fig. 1

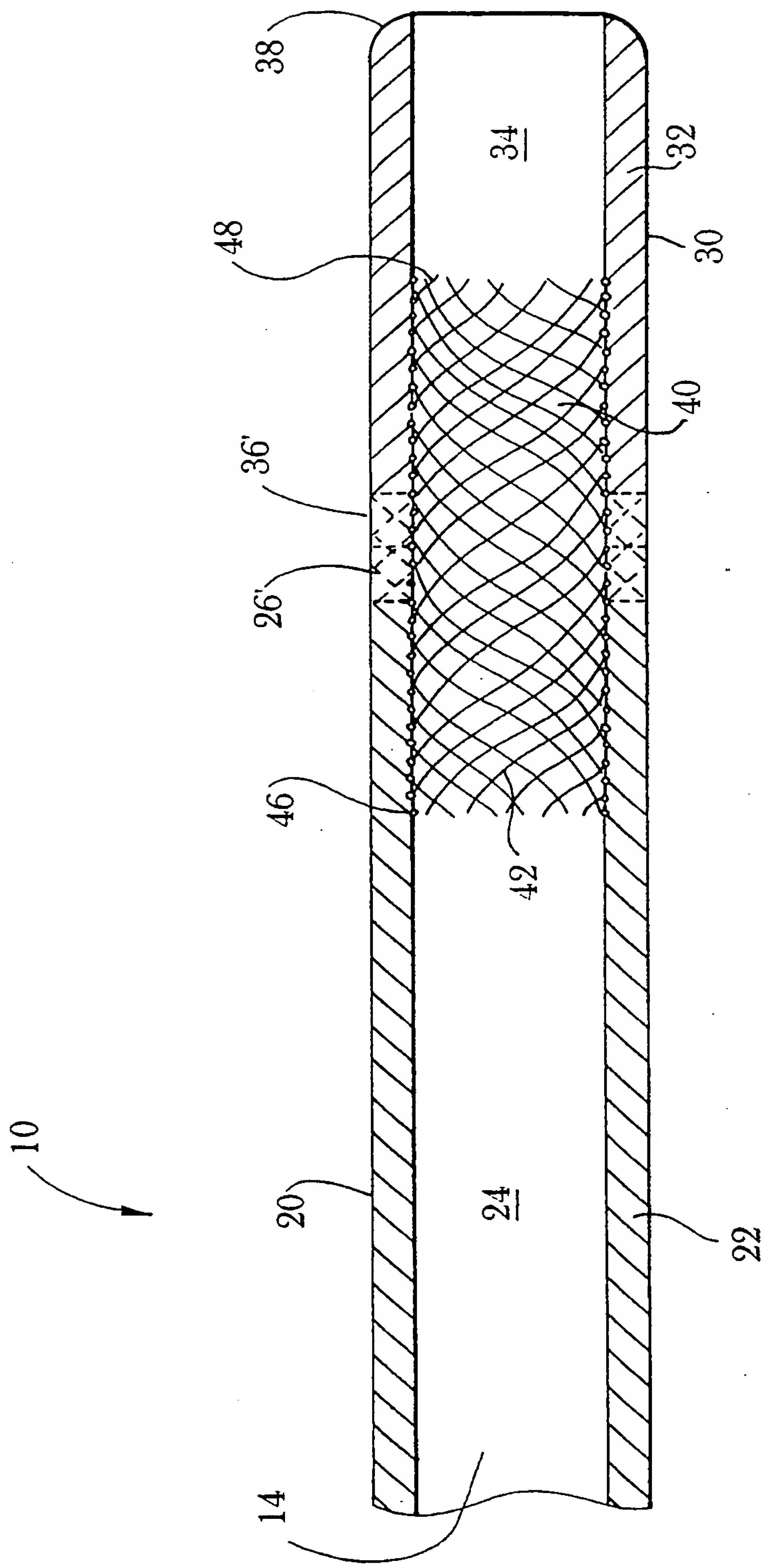


Fig. 2

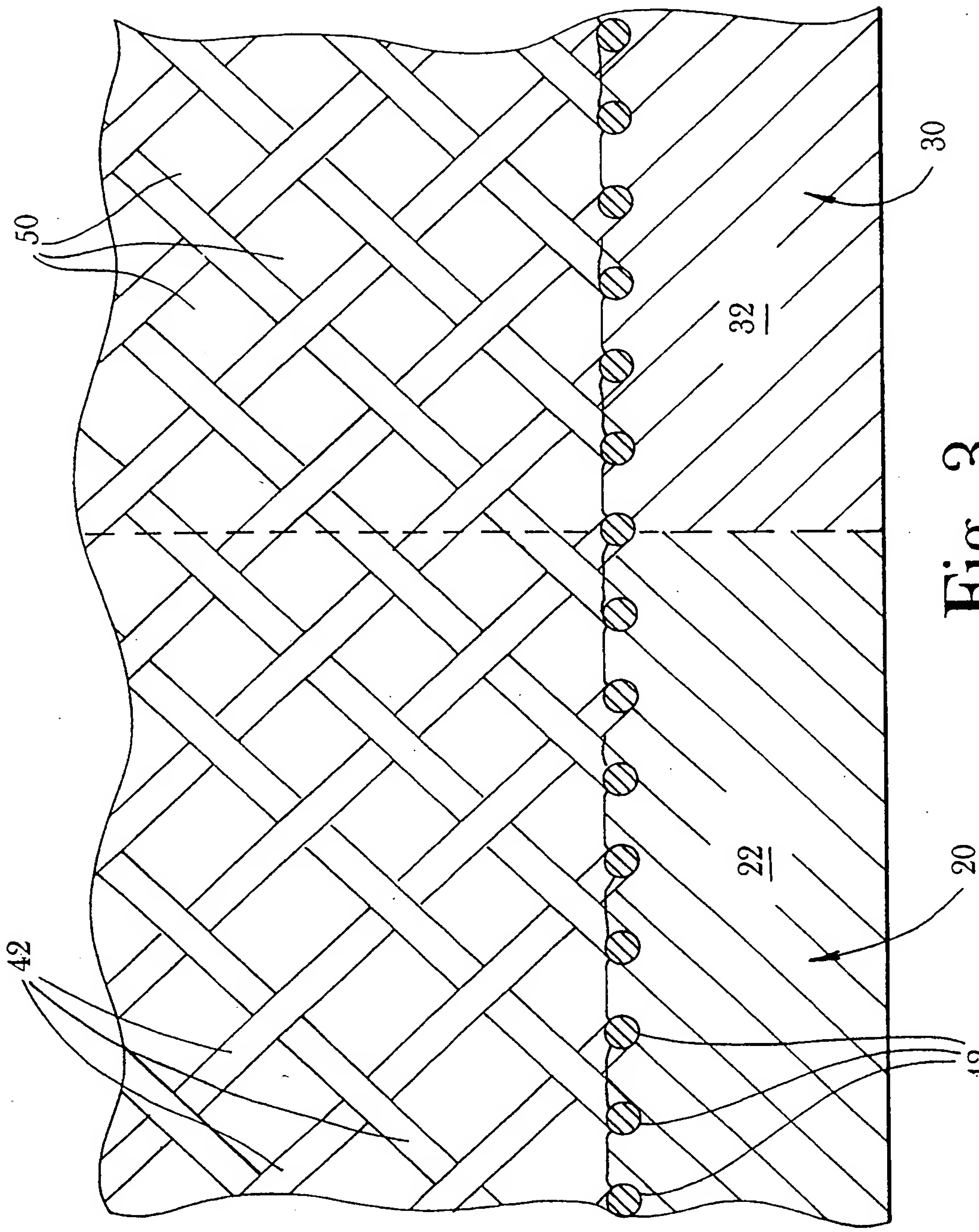


Fig. 3

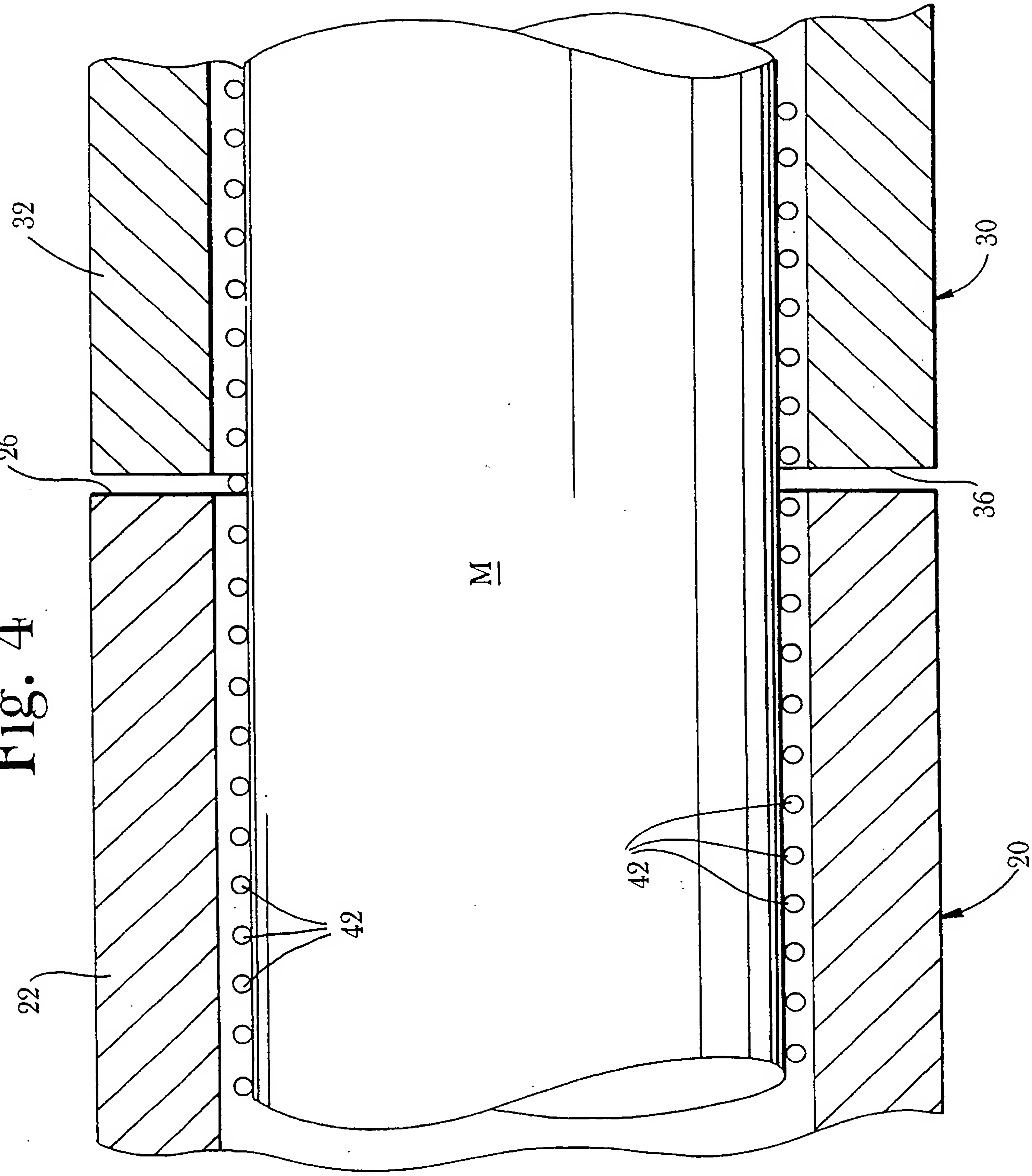


Fig. 4

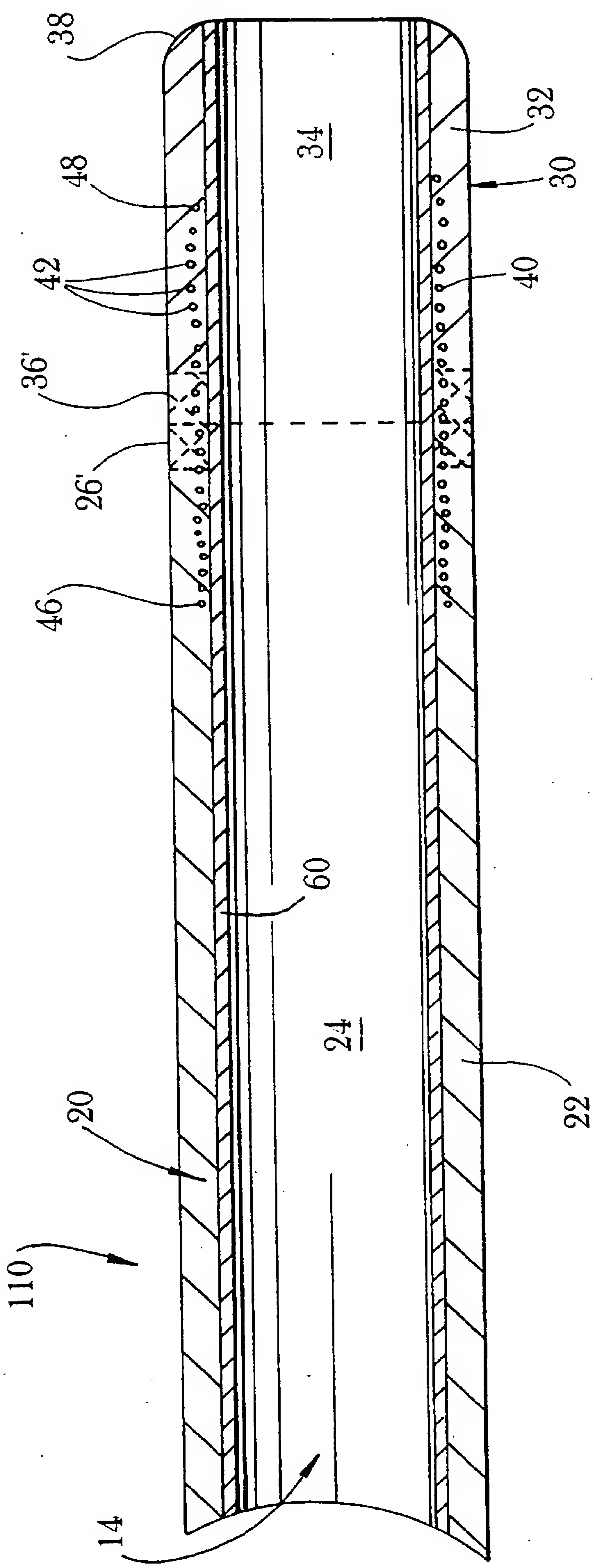
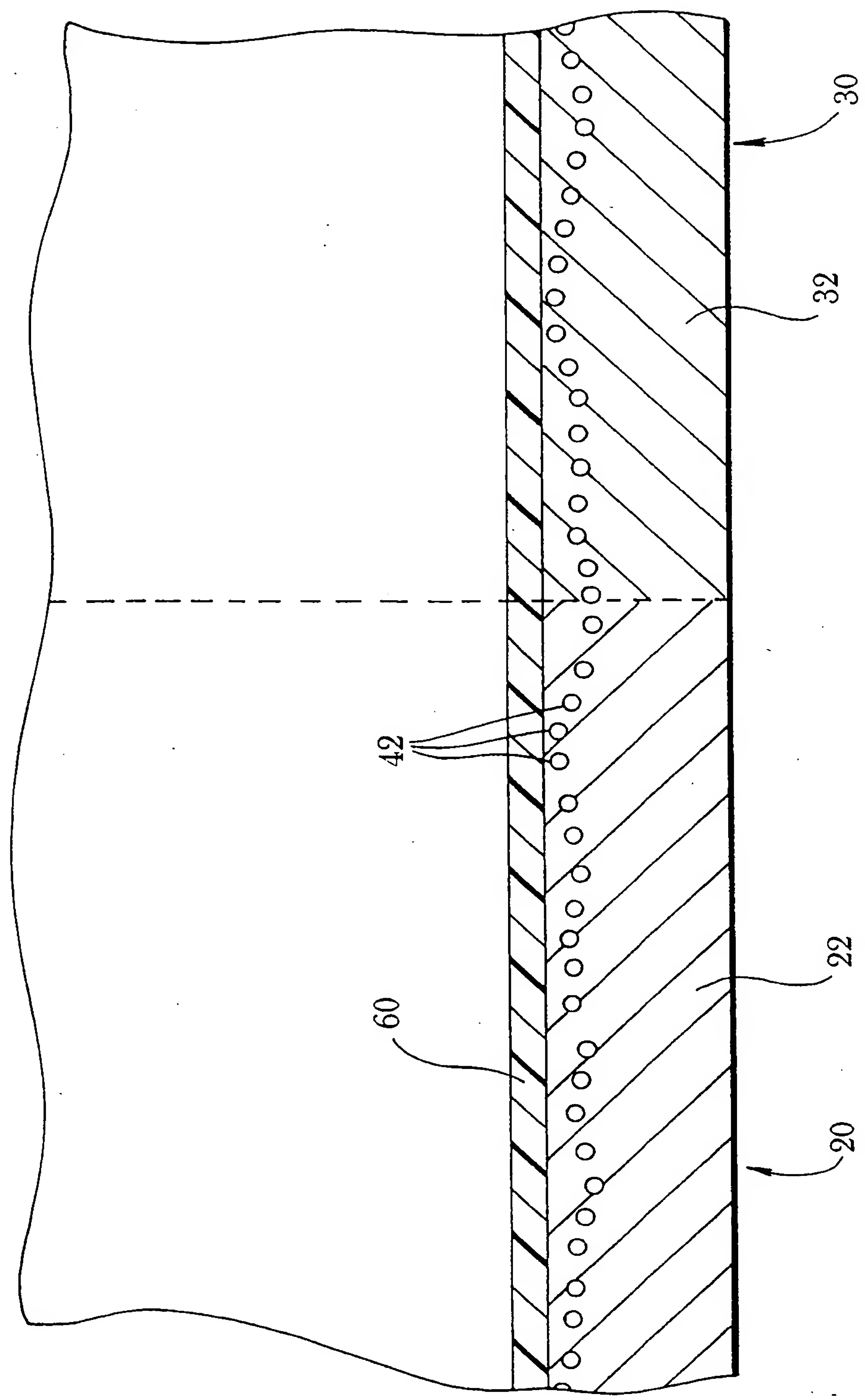


Fig. 5

Fig. 6



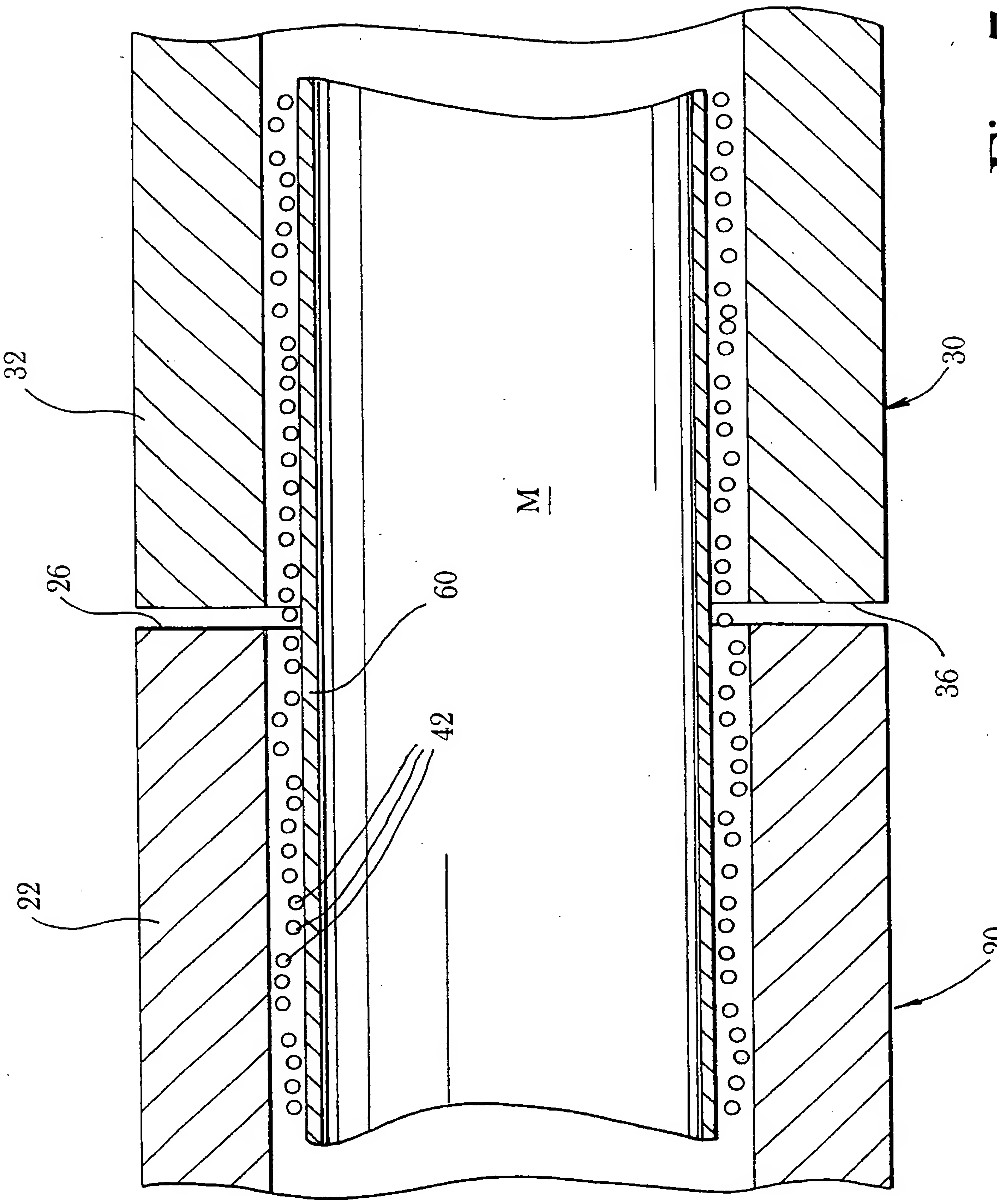


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/09154

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00
US CL :604/282
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/264, 280

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,254,107 A (SOLTESZ) 19 October 1993, col. 2,lines 5-64, col. 3 lines 3-63, col. 4 lines 34-68, col. 5 line 26 -to -col. 6 line 2.	1-5, 7, 8, 10-16, 18-20, 22, 24-30, 32, 33 --- 6, 17, 23, 34-36
X	US 3,598,126 A (HOELTZENBEIN) 10 August 1971, col. 2 lines 20-28, col. 2 lines 48-52, and col. 2 lines 66-75.	1, 5, 7-10
Y	US 4,385,635 A (RUIZ) 31 May 1983, col. 2 lines 42-58.	13

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search

21 JULY 1998

Date of mailing of the international search report

19 AUG 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer
SHARON ELIZABETH FINKEL

Telephone No. (703) 305-0154

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 3,416,531 A (EDWARDS) 17 December 1968, col. 2 line 71 to col. 3 line 52, col. 4 lines 30-50, and col. 7 lines 50-74.	1, 2, 4-7, 10-14, 16, 18-20, 22 ---------------- 24, 26-29, 32, 33
A,E	US 5,755,704 A (LUNN) 26 May 1998, col. 2 lines 6-9, col. 2 line 61 to col. 4 line 30, and col. 4 lines 50-67.	1-36